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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,859	10/29/2008	Yehoshua Yeshurun	1975/62	9876

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
08/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,859	YESHURUN ET AL.	
	Examiner	Art Unit	
	ANDREW GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-23 and 27-37* is/are rejected.

7)☒ Claim(s) *4-6 and 24-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 6/15/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 rejected under 35 U.S.C. 102(e) as being anticipated by Delmore et al (20030045837). Delmore discloses a microneedle device having a substrate (10), plurality of microneedles (20, see also 62), an abutment member (60), a displacement device configured (66; ¶97, 106) for generating a relative lateral sliding movement (¶44 – shearing forces, here after microneedles have been inserted into tissue, the displacement device allows for the user to exert a force parallel to the tissue surface to slide the microneedles along the tissue), where the microneedles define an effective area as claimed (Fig 1, 3, 6; ¶56).

4. Claims 21, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Safabash et al (6293925). Safabash et al discloses a microneedle injector (Figs 41-43), the microneedles having a substrate and plurality of microneedles ((col 7, lns 63-col 8, lns 16), abutment member (Figs 41-43), displacement device (Fig 41-43) configured for generating relative lateral sliding movement (col 4, lns 33-63), where a leading row contacts the biological barrier prior to a trailing row (Figs 41-43, where when a plurality of microneedles are inserted at an angle shown by Example in Figs 41-43 a first leading microneedle will contact the biological barrier prior to a trailing row of microneedles – where the microneedles here have been disclosed as being in series) , And at least part of the movement path having a non-zero component parallel to surface of substrate (insertion at an angle produces a non-zero component parallel to surface of substrate).

5. Claims 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Powell (6589202). Powell discloses a microneedle device having a substrate (ie. 78), plurality of microneedles (80), an abutment member (36), a displacement device (Fig 1) and defining a rotational path of movement (where as shown in Fig 8, there is a rotational path of movement of the fluid transport configuration (substrate and microneedles) relative to the abutment member where as the substrate and microneedles come off the spool they rotate with respect to the abutment member); see Fig 7 for cutting edge and penetrating tip.

6. Claims 21-23, 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lastovich et al (6440096). Lastovich et al discloses a microneedle device (Figures) having a substrate (84), microneedles (124) with cutting edges and penetrating tips (see

i.e. Fig 5), an abutment member as a suction cup (94; Fig 11), a displacement device being a suction arrangement (col 7, lns 61-col 8, lns 29) with a single one-dimensional movement of a suction plunger; an a fluid injection plunger (128; Fig 11) with priming port (98); where when suction is applied as shown in Fig 11-12 the surface of the biological skin is pulled upward and a relative lateral sliding movement between the fluid transport configuration exists (Figs 11-12; col 6, lns 32-37 explaining that lateral shear forces exist during use; and the examiner notes that as claimed – any generation of relative lateral sliding movement is sufficient to meet the limitation); also as shown in Fig 12, the biological surface exhibits a convex structure when suction is applied, here a center row of microneedles will be 'leading' row of microneedles and touch the biological barrier prior to a 'trailing' or outer row of microneedles.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3, 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmore et al in view of Lastovich et al. Delmore et al discloses the invention substantially as claimed except for expressly disclosing the suction arrangement as claimed. Lastovich et al teaches that it is known to have a suction arrangement as claimed (see above discussion) for the purpose of enhancing and maintaining penetration of the microneedles into the skin. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the displacement device as taught by Delmore et al with the suction arrangement as taught by Lastovich et al for the purpose of enhancing and maintaining penetration of the microneedles into the skin.

9. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmore et al in view of Powell. Delmore et al discloses the invention substantially as claimed except for expressly disclosing a rotational path of movement. Powell teaches that it is known to have a rotational path of movement as discussed above for the purpose of storing a plurality of microneedle fluid transport configurations on a spool. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedle fluid transport configuration as taught by Delmore et al with the plurality of microneedle fluid transport configurations on a spool as taught by Powell for the purpose of allowing successive treatment of a plurality of patients.

10. Claim 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmore et al in view of Safabash et al. Delmore et al discloses the invention substantially as claimed except for expressly disclosing generating a path of movement having a non-zero component parallel to said planar surface. Safabash et al teaches that it is known to have a non-zero component parallel to said planar surface (see above discussion) for the purpose of inserting the microneedles at a predetermined insertion angle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the displacement mechanism as taught by

Delmore et al with the angled displacement mechanism as taught by Safabash et al for the purpose of inserting the microneedles at a predetermined insertion angle.

11. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmore et al in view of Yeshurun et al (6533949). Delmore et al discloses the invention substantially as claimed except for expressly disclosing an asymmetrical microneedle. Yeshurun et al teaches that it is known to have an asymmetrical microneedle (Summary) for the purpose of preventing fracture of the microneedles during oblique insertion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microneedles as taught by delmore et al with the asymmetrical microneedles as taught by Yeshurun et al for the purpose of preventing fracture of the microneedles during oblique insertion.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claim 34 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7588552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

Allowable Subject Matter

14. Claims 4-6, 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767